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(71) Applicant; and
(72) Inventor: VAN DER ZON, Arnoldus, Theodorus, Maria [NL/NL]; Griegplein 188, NL-3122 VN Schiedam (NL).

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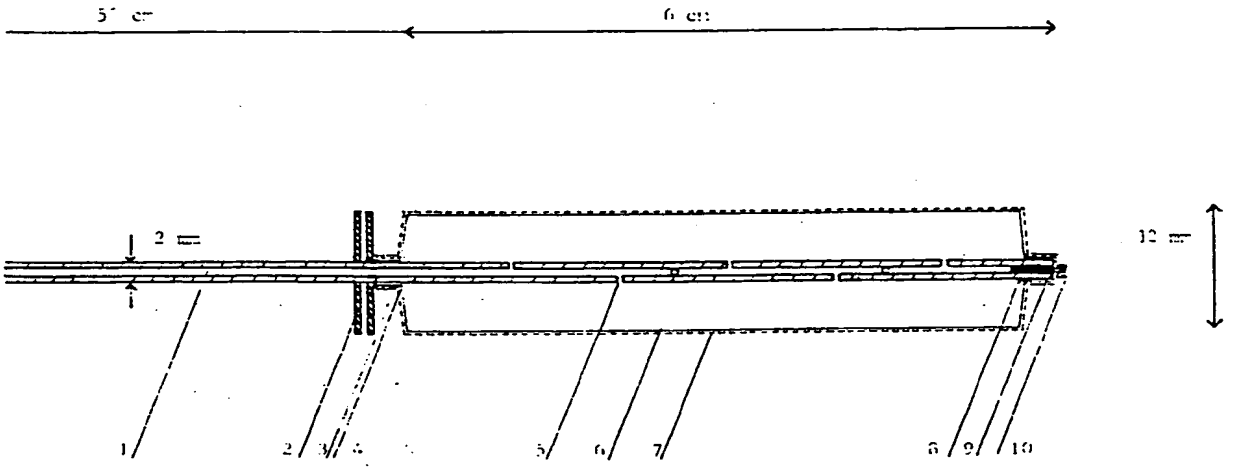

(57) Abstract

An inflatable balloon (6) encased in a thin, almost inelastic flexible, tightly woven nylon sleeve (7) of a cylindric shape, without seam and insertable in a collapsed state into the cervical canal or other body cavities for use in dilating and resistance measurement. One end of the balloon and its woven sleeve are attached to the tip (9) of an indistensible semirigid catheter while the other end (3) is attached to the same catheter (1) at a distance from its distal end. The lumens of the catheter and balloon are freely interconnected, through several openings (5) in the catheter wall. An increase in pressure in the balloon will cause uniform dilatation of the cervical canal, even at points of higher resistance and will not allow dumb-bell shaped dilatation. Small pressure changes within the balloon are independent on the characteristics of the balloon wall material and are closely related to the cervical resistance to dilatation.

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An armoured balloon for cervical dilatation and cervical resistance measurement.

An armoured balloon for cervical dilatation and cervical resistance measurement.

The invention concerns an armoured cervical dilatation and resistance measurement balloon.

The application of the invention regards the two medically important aspects of cervical closure. The cervix closes the uterine cavity leaving only a narrow canal. This cervical closure has to resist considerable force when the uterus enlarges greatly during pregnancy. The wall of the cervix uteri is therefore strong and thickened by a mass of connective tissue fibres.

In two ways the medical practitioner i.e. the gynaecologist is confrontated with the closure of the cervix. In the first place: every time it is necessary to perform an operation in the uterine cavity, the cervical canal is so narrow that dilatation is necessary for almost every operation. Indications for dilatation are as follows: curettages diagnostic as well as therapeutic, and abortion curettages), insertion of radium into the uterus and hysteroscopy.Secondly the practitioner is concerned with cervical closure of cervical incompetance is suspected. In this case the cervical canal will be stretch and the products of conception will not be retained during the course of development but are expelled from the cavity of the uterus either in premature labour or abortion. If the cervix is known to be incompenent it may be strengthened during pregnancy by encerclage with a synthetic fibre material. Outside the period of prenancy incompetence of the cervix can be evident of the cervical resistance will be too low during an attempt for artificial dilatation.

Well-known methods of cervical dilatation and measurement of incompetence.

Many techniques for cervical dilatation have been described over the years. A recent, alsmost complete, review of the literature can be found in the Populations Reports.[1] Few techniques have been described for measuring cervical incompetence.

All the literature available to us is reviewed.[2]
First all the different teechniques are described and secondly each technique is briefly explained in some detail.

1. Cervical dilatation procedures.
   1.1. hydrophilic substances which swell mostly in the shape of a sound.
   1.2. a serial dilatation with rods of increasing sizes.
   1.3. expanding steel dilators.
   1.4. vibradilators.
   1.5. dilation hydrostatic balloons.
   1.6. cervical softeners, for facilitating dilatation.
2. Techniques for measurement of cervical incompetence.
   2.1. hysterography : making visible the diameter of the cervical canal by X-ray photography after filling the cervical canal with radio-opaque contrast fluid.
   2.2. Hegartest: manual judgement of resistance to the introduction of Hegar rod No.8 into the uterus.
   2.3. mechanical Hegar probe: recording the force required to introduce a Hegar rod into the uterus.
   2.4. Expanding steel dilators.
   2.5. balloon dilatation pressure measurements.

1.1. Substances which swell.

1.1.1. Laminaria tents are hygroscopic and can swell to three or five times their original diameter. Disdavantages:the tents work slowly. There is a chance of damage to the cervix by introduction because the tents must be pushed into the canal, and when removed they are swollen like a dumb-bell. There is a relatively high risk of infection by a possible lack of sterility of the material and because of the long time required for the dilating process.

1.1.2. Devices made from the seed husk of Plantago ovata. Disadvantages: the cervix can be damaged by introducing them. The method works slowly. The desired dilatation is not always obtained.[3]

1.2. Serial dilating rods.

Rods are available in series of increasing diameters. Many kinds of materials are available among others wood, rubber and especially nowadays steel. Disdavantages: there is a chance of uterine perforation or cervical damage and the method is too painful to carry out without local or general anaesthesia.

1.3. Expanding dilators.

The blades force the cervical canal open. Disadvantages : there is a chance of uterine perforation or cervical damage and the method is too painful to carry out without local or general anaesthesia.

1.4. Vibra-dilators.

1.4.1. Steel tapered probes which dilate in steps by vibration. Disadvantages: In nulli-gravids it is now always effective. Because of the intense vibration the feel of direction disappears thus there is an increased chance of injuring the uterus. The method is too painful to apply without anaesthesia.[4]

1.5. Hydrostatic dilating balloons.

1.5.1. Balloons made of rubber are inserted in the cervical canal and then inflated with water to give pressure in the cervical canal. Disadvantages: during inflation the balloon acquires the shape of a dumb-bell, therefore there is no dilatation at the point with most resistance; also with increases of pressure the balloon may burst.

1.5.2. A modification of this balloon to disminish the danger of bursting is a surgical pump.[5] The balloon was put into a silk sack and after maximum filling the balloon acquires the shape of a ball. Disadvantages: the large insertion diameter, after inflating the balloon becomes a dumb-bell shape because of which no effective dilatation can be achieved. With this balloon resistance cannot be measured because during stretching out the rubber balloon the elastance of the wall of the balloon is measured.

1.5.3. An inflatable soft rubber device for dilatation of gravid uteri; this balloon can be inserted into the lower uterine segment and inflated with fluid. Inside the uterus the balloon induces labour, dilatation is also obtained after placing the balloon under traction. Disadvantage: limited application and it works slowly.[6]

1.5.4. A silicone rubber disposable dilatation balloon. Disadvantaggs: ineffective because of a dumb-bell shape, unsuitable for use with high pressure and too flexible to insert into a narrow cervical canal.[7]

2. Cervical incompetence measurement procedures.

2.1.1. Hysterography: demonstration of the width of the cervical canal with radio-opaque contrast fluid gives insufficient information about cervical closure because the photographs are not taken with the cervix under pressure.

2.2.1. Hegar test: the judgement of resistance to insertion of a Hegar rod number 8 (diameter 8 mm) is a subjective measure.

2.3. Recording of the force required for insertion of a steel rod.

2.3.1. Tapered steel dilators places on a spring.[8] Disadvantage:metal rods can injure the uterus.

2.3.2. Hegar rods fixed in the plunger stem of a plastic syringe. The syringe is filled with fluid and the Hegar rod is pushed into the cervical canal. The force required for this is recorded by way of a fluid-manometer.[11] Disadvantage: Although the required force can be given by increments, the insertion of steel rods into the uterus carries the risk of injury.

2.4.1. Expanding steel dilators.

A steel device with two or four ribs forces the cervix open mechanically an the required force is recorded with the aid of a transducer.[9] Disadvantages: steel expanding instruments could damage the uterus.

2.4.2 Tapered dilator heads placed on a holder; the required force is recored with the aid of a transducer.[10] Disad-

vantage: steel instruments could damage the uterus.

2.5.1. Balloon measurement . By the insertion of a highly complaing balloon into the cervix.[12] This balloon acquires the shape of a dumb-bell in the cervical canal and measures the elasticity of the balloon itself rather than the resistance of the cervical wall.

Dilatation and measurement with the aid of a balloon.

The disadvantages of the known balloon constructions are caused because the balloon itself is elastic. Thus the balloon get the shape of a dumb-bell while trying to measure the resistance of the cervix against dilatation and only the elasticity of the balloon wall is measured. The cervix does not dilate or does so insufficiently because the balloon swells especially outside the cervical canal. Because of this possibility of a local swelling out of the balloon-wall with the increase volume the pressure increase required for dilatation of the cervix is not attained. The purpose of the invention is a balloon construction without these disadvantages. This purpose is reached by protecting the balloon with a cylindric round woven sleeve. This sleeve surrounds the balloon completely and is fixed to the filling-catheter of the balloon. See Figure 1. The catheter is made of a strong semiriged material, for instance polyurethane. The length of the catheter is about 55 centimetres, the diameter of the catheter is 2 millimetres, the lumen is 0.5 millimetres (Figure 1-1). There is a fixation (Figure 1-2) plate with which the balloon can be held in situ by, for instance a supporting bar connected with a tenaculum which is fixed on the cervix. This plate also prevents the balloon from slipping too far into the cervical canal. The end of the cylindric shaped sleeve is fixed on the top of the strong semiriged filling catheter. The other end of the sleeve is fixed around the filling catheter at the point of entering the balloon which is at a distance of for instance 6 centimetres from the top (Figure 1-3). In this way the sleeve covers the whole balloon. The inner balloon is glued and tied to the catheter

for fixation and waterproof enclosure (Figure 1-4).
The catheter wall inside the balloon contains several openings of a diameter of 0,5 millimetres for filling the balloon (Figure 1 -5). The inside balloon is a condom with a diameter of 3.5 centimetres, length 7 centimetres, consisting of natural latex : the thickness of the condom wall is 0,07 millimetre (Figure 1 - 6)
The cylindric woven sleeve consists of a round-woven 100 denier polyamide multifilament thread. The thickness of the sleeve wall is 0,1 millimetre (Figure 1 - 7).
The top of the catheter is closed with a little plug (Figure 1-8). Fixation of the balloon and sleeve on the top of the catheter: glued and tied (Figure 1 - 9).
The top of the balloon coincides with the glued and tied end of the sleeve (Figure 1 -10). Mersilene thread of 2 x 0 filum polyestericum was used for the ties.
The balloon described on the previous pages is drawn and enlarged twice in Figure 1. Properties of this armoured balloon are to resist pressures of over 10 atmospheres . During filling of the balloon in the air to this pressure the balloon keeps its cylindric shape. In an empty and collapsed state the external diameter of the entire unit, that is the filling catheter with balloon and sleeve, is 4 millimetre. In this collapsed state the balloon is inserted into the cervix. After that gradual filling takes place. During the filling the balloon follows the contours of the wall of the cervical canal. This may be shown if the filling takes place with a contrast fluid under X-ray control. During filling the pressure in the balloon increases. The rate of pressure-rise depends on the rapidity of filling (fixed infusion rate with an infusion pump may be used) and the resistance of the cervix against dilatation may be measured. Soon after the beginning of filling a narrowing remains for some time at the point of maximum resistance in the cervical canal (this may be visible on a X-ray screen by filling the balloon with a radio-opaque

contrast fluid). With increasing pressure in the balloon this narrowing disappears and the balloon adopts its cylindrical shape. In this way a quick and sufficient dilatation is obtained. At the same time the resistance of the cervix to dilatation can be determined by measuring and recording the balloon pressure during filling. The balloon and the filling fluid may be sterilised. This gradual hydrostatic dilatation is less painful and there is less damage to the cervix than the stepwise dilatation using steel rods. In this way the entire balloon is covered by its woven sleeve. The strengthening of the balloon may be achieved in either one of two ways, depending upon the proposed use of it. If dilatation and measurement of cervical resistance to dilatation are desirable the balloon should be made of a thin watertight flexible material, placed freely within a flexible non elastic sleeve.

If dilatation is the only objective, the sleeve itself could be made waterproof by impregnation with a suitable material and thus perform the function of the balloon itself, precluding the necessity of an inside balloon.

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We are describing a technique by which the cervix may be opened and also the force required so to do may be measured. The principle is that a balloon is inserted into the cervical canal and is filled with a fluid. The pressure in the system may be measured. The principle of hydrostatic balloon dilatation is already well known, but previously the use of balloons in the cervical canal has been unsatisfactory, because of the tendency of the balloons to form a dumb-bell shape at areas of high and low resistance thus producing a non uniform dilatation. This is especially marked in the cervical canal, where the cavity of the uterus and cervical canal near the external os offer low

resistance and hence receive excessive dilatation, whereas the junction of the cervical canal and the uterine cavity (the internal os) offers high resistance and hence receives minimal dilatation. The consequences of the balloon adopting the dumbbell configuration are first an unequal and inadequate dilatation of the entire cervical canal, and secondly a false picture of the systems hydrodynamics, which are more closely related to the elacticity of the balloon than the resistance of the cervix to dilatation.

What is claimed is:

a balloon for the dilatation of the cervical canal and the measurement of the resistance to that dilatation, charactarised in that the balloon is armoured by the encasement in a thin, almost inelastic, flexible, tightly woven nylon sleeve of a cylindrical shape and without seam. This ensures that the armoured balloon inflates uniformly along its length to become a cylinder. Thus an increase in pressure in the balloon will cause uniform dilatation of the cervical canal, even at points of higher resistance and will not allow dumb-bell formation at points of low resistance. Small pressure changes within the balloon are independant of the characteristics of the balloon material and are closely related to the resistance to dilatation of the cervical wall. One end of the balloon and its woven sleeve are firmly attached to the tip of a non-distensible semirigid catheter while the other end is firmly attached to the same catheter at a point of for instance six centimetres (6 cm) from its distal end. The lumens of the catheter and balloon are freely interconnected. In this way the entire balloon is covered by its woven sleeve. The strengthening of the balloon may be achieved in either one of two ways, depending upon the proposed use of it. If dilatation and measurement of cervical resistance to dilatation are desirable the balloon should be made of a thin waterproof flexible material placed freely within a flexible nonelastic sleeve. If dilatation is the only onjective, the sleeve itself could be made waterproof by impregnation with a suitable material and thus performs the function of a balloon itself, precluding the necessity of an inside balloon.

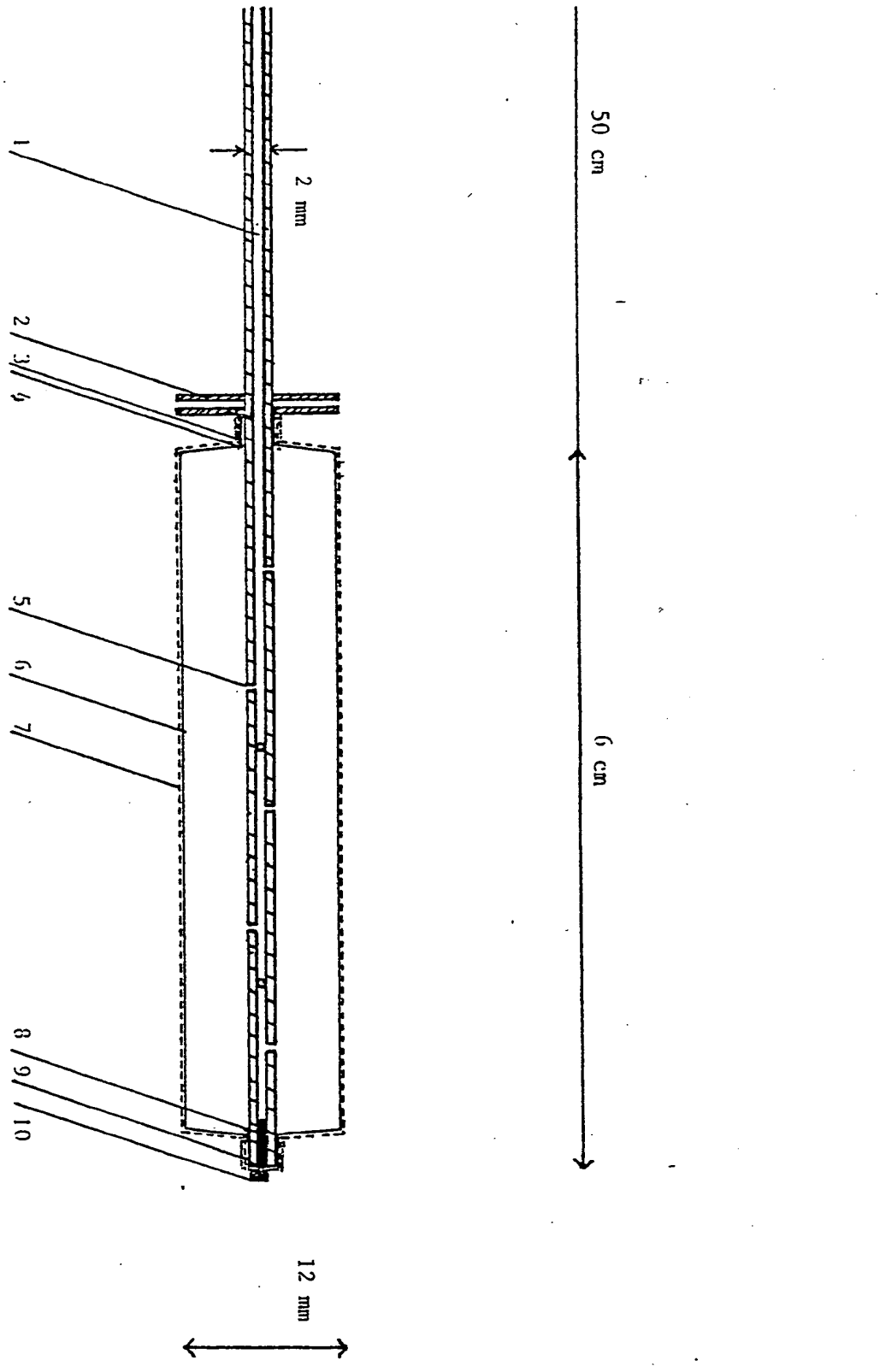

FIGURE 1

Scale ? : 1

INTERNATIONAL SEARCH REPORT

International Application No PCT/NL 80/00034

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[3]: A 61 B 17/42; A 61 M 29/00; A 61 B 5/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
Int.Cl.[3]	A 61 B; A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO SE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [13]
	CH, A, 346971, published July 30, 1960, see figures and page 2, lines 12-55, Sokol	1
	DE, C, 526423, published July 22, 1928, see the whole document, Monte Lloyd Corp.	1
A	US, A, 2024301, published December 17, 1935, see figures and page 2, left-hand column, lines 23-27, Norwood	1
A	FR, A, 2220284, published October 4, 1974, see figures and claim, Ortho Pharm. Corp. corresponding to NL, A, 3402762 US, A, 3900033 US, A, 4137922	1

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
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